

## **REMARKS**

### **Claims**

Claims 1–63 are pending with claims 64–70 added by this paper.

The claim identifiers recited herein are not to be construed that Applicants' acquiesce to the pending restriction requirement. Should the restriction requirement be withdrawn, either partially or entirely, the status of the claims will be amended to reflect such changes.

### **Amendments**

The claims have been amended to use language in accordance with conventional US practice and to correct obvious typographical errors. Use claims have been converted into US process claims.

The amendment of present claim 18 and claim 21 is self-explanatory.

The subject matter cancelled from claim 4 is now recited in new claim 64. The subject matter cancelled from claim 5 is now recited in new claim 65. The subject matter cancelled from claim 8 is now recited in new claim 66. The subject matter cancelled from claim 13 is now recited in new claim 67. The subject matter cancelled from claim 16 is now recited in new claim 68. The subject matter cancelled from claim 38 is now recited in new claims 69 and 70.

It is respectfully submitted that the amendments do not recite new matter. Entry thereof is respectfully requested.

### **Use claims**

Independent claims 1, 6 and 30, along with claims which either directly or indirectly depend thereon, have been converted into US process claims. The claims are directed to a method of using the molecules of the instant invention. The Examiner is respectfully requested to examine the claims on the merits.

### **Restriction/Election**

In response to this Restriction Requirement mailed November 28, 2008, Applicants hereby elect, with traverse, Group I (claims 1-43), drawn to a method of using a neurturin product or a modulator/effector of a neurturin product for the manufacture of a medicament to stimulate and/or induce differentiation of insulin-producing cells from progenitor cells.

The examiner's justification for the restriction is that the "claims do not share a special technical feature over the art because Johnson et al. (US 5,739,307) describe neurturin and cDNA sequences encoding neurturin." However, Johnson does not disclose the ability of neurturin to

promote differentiation of progenitor cells in to insulin-secreting cells. As such, the basis for this restriction requirement is misplaced.

The Patent Office is courteously requested to reconsider the Restriction Requirement, inasmuch as it is submitted that the entirety of the present claims possesses unity of invention under 37 C.F.R. §1.499. The claims in the instant application involve related subject matter, for example, a method for using a neururin product or a modulator/effector thereof. All the claims would comprise overlapping subject matter and it would not be an undue burden on the Examiner to carry out a search of the full scope of the original claims. "If search and examination of an entire application can be made without serious burden, the examiner *must* examine it on the merits, even though it includes claims to independent or distinct invention." (Emphasis added.) See, M.P.E.P. §803. Accordingly, it is respectfully submitted that the restriction be withdrawn.

Should the restriction requirement still be maintained, Applicants request that at a minimum, the claims of Group III (claims 55–58) be examined with the claims of the elected Group I because they linked by a common inventive concept.

#### Election of species

Page 4 of the outstanding Office Action requires that Applicants make an election of species. Insofar as the Office Action fails to provide any rationale as to why search/examination of anything *beyond* a single species would constitute an undue burden, this nebulous requirement is without merit. However, in order to comply with the election of species requirement, Applicants elect, with traverse, the following species/nested species:

- (a) Applicants elect embryonic stem cells as recited in present claims 3 and 36;
- (b) Applicants elect regeneration of insulin-producing cells, as recited in present claim 6;
- (c) Applicants elect diabetes type I as recited in present claims 11, 12 and 33;
- (d) Applicants elect pancreatic diseases, as recited in present claim 27;
- (e) Applicants elect insulin production in response to glucose, as recited in present claim 39;
- (f) Applicants elect transplantation, as recited in present claim 48.

The following claims read on the elected Group/species: claims 1–7, 9–11, 16–23, 27 and new claim 30.

With respect to the cells, Applicants submit the types of cells recited in present claim 3 are pluripotent cells whose meaning is well-appreciated in the art (e.g., capable of differentiating into a

diverse range of specialized cells). As such, the requirement that Applicants elect a single type of cells is respectfully traversed.

Applicants further submit that the diseases recited in present claim 11 are related by a single inventive concept. As explicitly stated in the paragraphs bridging pages 2 and 3 of the present specification, the three types of diabetic diseases (i.e., diabetes type I, LADA, or progressed diabetes type II) are all characterized by a deficiency in functional beta cells. As such, the Examiner is respectfully requested to examine the subject matter of these claims in their entirety.

Applicants reserve the right to file one or more divisional applications directed to non-elected inventions.

The Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

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Attorney Docket No.: WEICKM-0058

Date: January 10, 2009